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| 10/802,520 | 03/16/2004 | Eric Leopold | MICRU:68082 | 3981 |
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| FULWIDER PATTON LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE, TENTH FLOOR LOS ANGELES, CA 90045 | | | EXAMINER RYCKMAN, MELISSA K | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/802,520

Applicant(s)

LEOPOLD ET AL.

Examiner

Melissa Ryckman

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This office action is in response to claims filed 6/18/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new matter is regarding the placement of the slot, specifically a longitudinal slot formed in the upper wall of the "distal portion of the" elongated tubular member, and "removal of the embolic coil and distal segment of the pusher member through the slot" and "less than about 10 cm with no slot".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz as a matter of design choice and further in view of Ahmed (5,293,713) and further as a matter of design choice.

Diaz teaches a device comprising the following:

- A sheath (12) in combination with a vasoocclusive device (50)
- the vasoocclusive device including an assembly of a flexible pusher member (44) including proximal and distal segments and an embolic coil (50) at the distal segment of the pusher member (Figs. 4-6), the assembly being adapted to be inserted into a portion of a vasculature for occluding a portion of the vasculature for use in interventional therapy and vascular surgery, the sheath comprising:
 - a hollow, elongated tubular member (14) having proximal and distal portions, opposing upper and lower walls,
 - opposing side walls (12)
 - a longitudinal interior channel (14)

- o the sheath (12) being attached to the proximal segment (attached via 24, in Fig. 1) of the flexible pusher member (44)
- extending a majority of the length of elongated tubular member leaving less than about 10cm with no slot (Page 4, paragraph 42)
- the slot having opposing sides with inner side surfaces extending through the upper wall of the elongated tubular member leading to the interior channel (12) permitting introduction of the vasoocclusive device into the interior channel removal of the embolic coil and distal segment of the pusher member through the slot (this is inherent because the coil is inserted through the slot).
- wherein the outside diameter is approximately .003 inches, and wherein the inside diameter is slightly greater than that of a deployment catheter (Page 4, paragraph 42), corresponding to the lower wall of the hollow, elongated tubular member (12) being about 0.002 to 0.004 inches thick to allow the opposing sides of the slot of the hollow, elongated tubular member to flex outwardly to allow the slot to open to accept the vasoocclusive device (Page 2, paragraph 14).
- wherein the hollow, elongated tubular member is formed from a polymer material with a durometer in the range of about 50D and 70D (page 4, paragraph 42).
High-density polyethylene is a type of thermoplastic polymer and has a durometer of between 61D and 63D, falling in the disclosed range.

Diaz fails to teach a longitudinal slot (36) formed in the upper wall of the distal portion of the elongated tubular member and a v-shape configured guide. It is a matter

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of design choice to have the distal portion of the elongated tubular member have a longitudinal slot, the specification of the current application does not include a reason for the placement of the slot being at the distal portion, the device of Diaz would perform equally as well with a longitudinal slot at the distal portion of the elongated tubular member.

Ahmed teaches the use of angled winged flanges in order to enhance guiding the element as the element is pushed through the opening (Col. 2 lines 68-70). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Diaz with the winged flanges as taught by Ahmed in order to enhance guiding the element as the element is pushed through the opening.

Ahmed fails to disclose the size of the interior angle between the wings, however, Ahmed does disclose that it should be at least thirty degrees, and further the angle used is sufficient to perform the function of a guide as illustrated in figure 2. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angles of the opening between 110 to 150 degrees, a working range as disclosed by the applicant, since the device as disclosed by Ahmed performs equally well as a guide without a specific angle range. Further, it has been held that where the general condition of the claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 6/18/07 have been fully considered but they are not persuasive. The applicant generally argues the following:

- the sheath is not attached to the flexible pusher member
- the function of the slot of Diaz is different than the function of the current application

The examiner respectfully disagrees with the applicant. The sheath is attached to the flexible pusher member at the proximal segment of the pusher member by using tab 24 (Fig. 1). The structure of the slot is not clearly defined to overcome Diaz, the slot of Diaz is capable of performing the function of the current invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR


(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER